DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FOI

JUL - 2 1997

TRANSMITTED VIA FACSIMILE

Ellen R. Westrick
Senior Director, Office of Medical/Legal
Merck & Co., Inc.
P.O. Box 4, WP37B-113
West Point, Pennsylvania 19486

Re: **NDA 20-560**
Fosamax (alendronate sodium tablets)
MACMIS ID #5575

Dear Ms. Westrick:

Reference is made to Merck & Co. Inc.'s (Merck) June 6, 1997, FDA form 2253 submission for Fosamax. This material consists of a brochure customized for Blue Cross Blue Shield for Georgia (#974652) titled "Are you one of 20 million American women with osteoporosis."

The Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed this material and has determined that it is misleading and in violation of the Federal Food, Drug, and Cosmetic Act and applicable regulations for the following reasons:

. The headline on page two, "Menopause is the single most important cause of osteoporosis" is false because although menopause is a factor contributing to the development of osteoporosis, menopause alone does not cause osteoporosis. Further, the headline is misleading because it overstates the population eligible for therapy with Fosamax by implying that all women develop osteoporosis at menopause. DDMAC has commented on this issue previously in our December 15, 1995, advisory letter and most recently in our April 14, 1997, advisory letter for Fosamax.

DDMAC requests that Merck immediately discontinue the dissemination and use of this brochure and other promotional materials that contain similar themes. DDMAC requests that Merck submit a written response to this letter no later than

July 18, 1997, including Merck's plan to comply with DDMAC's request.

If Merck has further comments or issues, please contact me at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857.

In all future correspondence related to this matter, please refer to MACMIS ID #5575 and the NDA number.

Sincerely,

Anne M. Reb, MS, NP
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications